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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/810,660      03/19/2001      Roman Efrain Vasquez Lipi      2119-109      9057

6449      7590      06/16/2004

ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

YU, GINA C

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/810,660	<b>Applicant(s)</b> VASQUEZ LIPI, ROMAN EFRAIN	
	<b>Examiner</b> Gina C. Yu	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-15,17,18 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,17,18 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2004 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is rejected because the claim limitation is inconsistent with the scope of the base claim, claim 1. Claim 1, by reciting, "consisting of", excludes all other components not recited in the claim. While claim 1 recites a "pharmaceutically acceptable excipient", examiner views that incorporating additional components in the excipient as in claim 18 essentially broadens the scope of claim 1 because any additional ingredients can be added in the "excipient".

### ***Claim Rejections - 35 USC § 103***

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 4-15, 17, 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over George (US 3431340) in view of Soto (Derwent Acc. No. 1984-271531), Arhens (US 3825563), Kaplan (US 5047232), and Slimak (US 6099866).

George teaches that castor oil and cod liver oil are well known for the treatment of burns. See col. 2, lines 1 – 61. The reference teaches a topical composition consisting essentially of 35-65 % by weight of castor oil and 35-65 % by weight of cod liver oil. The reference recites, “[t]he castor oil prevents the growth of scar tissue, and the fish oil controls the caustic action of the castor oil, while at the same time promoting the healing of the wounds.” See col. 2, lines 45 – 48; see also col. 2, lines 15 – 26. The reference also teaches that cod liver oil contains at least 1000 USP units of vitamin A and 100 USP units of vitamin D per gram. See col. 2, lines 21 – 26. The reference further teaches that “[a]dditional quantities of vehicles, vitamins, and other fortifying substances may be as required.” See col. 2, lines 9-14. See instant claims 6-8, 10-13.

George fails to teach the remaining components recited in claim 1.

Soto teaches method of treating skin injuries by topically applying a composition comprising essentially of olive oil (100 parts) and beeswax (10 parts) as the principal ingredients. See abstract. The reference also teaches that one of more aromatic plant oils can be further incorporated therein.

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Ahrens teaches a vitamin E (d-alpha-tocopheryl-acid-succinate) cream compositions having sweet almond oil and mineral oil (petrolatum) base. The reference teaches that the compositions provide stable and economic means to provide the therapeutic effects of vitamin E. See the amounts of the ingredients in Tables 1, 2, and 3. See instant claim 17. The reference specifically teaches that the application of Vitamin E to burn skin "immediately" relieved pain, renewed the skin layers afterwards and provided healing effects on the third day. See col. 8, lines 7 – 21. See instant claims 9, 14, and 15.

Kaplan teaches that almond oil and castor oil are emollients well known to one having ordinary skill in the art. See col. 3, lines 66-67; col. 4, lines 34 – 3. Specific examples that these oils are used in mineral oil-based composition are shown in Examples 1, 2, 3, and 13. See instant claim 17. The examples also employ vitamin E in the weight amount of 0.1 -1 % by weight. See instant claim 9.

Slimak teaches a composition comprising beeswax and oil, with or without water, useful for treating topical wounds including burns. See abstract. The reference specifically provides motivation to limit the ingredients to wax, oil, and water, due to possibility of allergic reactions. See col. 12, lines 37 – 43. The reference teaches that antibiotics may be added. See col. 13, lines 10 – 17. See instant claim 22. Slimak teaches to combine the beeswax with plant oils and suggest that animal oil can be further added therein. See col. 12, lines 16 – 44. Almond, olive, sunflower, and mineral oils are disclosed. It is well known in the art that sunflower oil also contains vitamin E. The reference further teaches that

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“an oil similar to the plant source of the wax” is preferably used, which include sunflower and olive oils. Accordingly, a skilled artisan would have been motivated to select these oils to combine with the beeswax composition. The Slimak reference teaches when water, the excipient in this case, is used, the volume ratio of wax:oil:water can range from 1:0.1:0 to 1:6:6 to produce a soft, easily applicable composition for topical application to the skin. See col. 10, lines 55 – 60. See instant claim 2.

While the specific weight amount of the each of oil components are not taught as recited in the instant claim, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in the combined references, examiner views that one having ordinary skill in the art would have discovered the optimum or workable weight amount of the ingredients by routine experimentation. The skilled artisan would have considered the cost of the ingredients or the rheology or spreadability of the final product, as suggested by Slimak. See col. 10, lines 55 – 60. See also In re Boesch, 205 U.S.P.Q. 215 (C.C.P.A. 198) (holding it is within the skill in the art to select optimal parameters, such as amount)

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in

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the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

As shown by the recited teachings in the George, Soto, Ahren, and Kaplan. As shown by the references, the instant claims define the concomitant use of conventional therapeutic agents known for burn treatment. It would follow that the combination of beeswax, olive oil, castor oil, and cod liver oil and the method of use thereof is prima facie obvious.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the George composition by adding the additional ingredients of the secondary references because

- 1) all references are directed to burn skin treatment compositions;
- 2) George specifically teaches to further incorporate "vehicles, vitamins, and other fortifying substances" to the castor oil/cod liver oil composition;
- 3) the skilled artisan would have had expectation that addition of olive oil and beeswax have additive effect in burn skin treatment composition, as taught by Soto;
- 4) the skilled artisan would have expected that further addition of petrolatum and almond oil to mix with vitamin E composition produces a stable therapeutic composition with enhanced healing effect on burn skin, as taught by Ahren;
- 5) the skilled artisan would have also expected that using natural oil such as sunflower oil for beeswax and further adding preservative would successfully produce a further stable burn treatment composition with an enhanced effectiveness, as taught by Slimak.

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2. Claims 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over George, Soto, Arhens, and Slimak as applied to claims 1, 2, 4-15, 17, 24-27 above, and further in view of Martin (US 5874479).

The combined references fail to teach stearic acid and BHT.

Martin teaches topical wound-healing compositions useful for, among others, healing of burns. See col. 23, lines 1 –9. Martin teaches that stearic acid is one of “the most common saturated fatty acids” required for the repair of cellular membranes and production of new cells. See col. 14, lines 21 – 64. See instant claim 18. The reference further teaches that BHT is an art-recognized preservative. See col. 13, lines 53-54. See instant claim 23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding well-known fatty acids such as stearic acid, as motivated by Martin, because 1) Slimak teaches to add a preservative; and 2) the skilled artisan would have expected to successfully produce an enhanced wound-treatment composition which is effective in repairing cell membrane and producing new cells. The motivation to use a conventional preservative well known in pharmaceutical art such as BHT would have been also obvious to the routineer in view of Martin.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4-15, 17, 18, and 22-27 have been considered but are moot in view of the new ground(s) of rejection in part and unpersuasive in part.



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Applicant argues that the motivation for combining the cited references is merely that the components are "well known and commonly used in the art". Applicant argues that combining components which serve as carrier or vehicles only duplicates the function and would not motivated a skilled artisan to combine the them. Specifically, applicant states that the present invention is a composition of beeswax in pharmaceutically acceptable vehicle, and assert that a routineer would not need additional vehicles, such as cod liver oils, for the wax. Examiner respectfully disagrees. The reference are all directed to specific utility – i.e., treating burn skin. George reference specifically teaches that cod liver specifically is required to prevent caustic effects of the castor oil and to enhance the therapeutic effects, which provide ample motivation to the routineer to employ that specific ingredient in the burn treatment composition. The reference also specifically teaches to incorporate not only additional vehicle, but vitamins and fortifying agents also, which would have certainly motivated the routineer to look and add additional active ingredients for burn treatments.

### ***Conclusion***

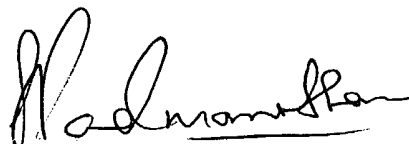
No claims are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**